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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,511	12/22/2000	Douglas G. Clark	VTN-527	1745
7590 08/04/2004				
Philip S. Johnson, Esq. Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003		EXAMINER SCHWARTZ, JORDAN MARC		
		ART UNIT PAPER NUMBER 2873		

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,511

Applicant(s)

CLARK ET AL.

Examiner

Jordan M. Schwartz

Art Unit

2873

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8,10,11,14-29 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8,10,11,14-29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1 and 25-26 (and dependent claims 2-4, 8, 10-11, 14-24, 27-29, 31-36) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1 and 25-26, that part of the claim stating “a translucent color zone that overlays the lens wearer’s iris” renders the claims vague and indefinite because it is not clear if applicant means “that overlays a portion of the lens wearer’s iris” or if applicant means “that overlays the entirety of the lens wearer’s iris”. If the former is the intended meaning then the Rawlings’121 and Knapp’188 rejections set forth in the prior office action would still be applicable. However, based upon applicant’s arguments of May 24, 2004, in which applicant is arguing that Rawlings’121 and Knapp’188 have intermittent areas of color, applicant apparently means, “that overlays the entirety of the lens wearer’s iris” and this is the assumed meaning for purposes of examination. However, claiming “a translucent color zone that overlays the entirety of the lens wearer’s iris, the translucent color zone comprising color throughout the entirety of the translucent color zone” creates prohibited new matter as set forth in the rejection below.

Claims 1 and 25-26 (and dependent claims 2-4, 8, 10-11, 14-24, 27-29, 31-36) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claiming “a translucent color zone that overlays the entirety of the lens wearer’s iris, the translucent color zone comprising color throughout the entirety of the translucent color zone” (which is the assumed meaning as stated above) creates prohibited new matter and is not supported by the specification and claims as originally filed. Specifically, applicant states that there is support for this assumed meaning in Figures 1, 5, 9 and the specification, page 4, lines 24-30.

However, Figure 1 apparently shows the translucent color zone having interspersed clear areas i.e. intermittent color. Likewise, Figure 5 has clear wavy areas throughout the color area and therefore does not disclose, “color throughout the entirety of the translucent color zone”. Figure 9 doesn’t really show any translucent color zone at all and if anything shows a few colored dots. Therefore, none of the Figures support “a translucent color zone that overlays the entirety of the lens wearer’s iris, the translucent color zone comprising color throughout the entirety of the translucent color zone”.

Likewise, page 4, lines 24-30 of the specification merely discusses a base layer “10” but there is nothing within the specification or Figures to support the claimed “a translucent color zone that overlays the entirety of the lens wearer’s iris, the translucent color zone comprising color throughout the entirety of the translucent color zone” and therefore this assumed meaning based upon applicant’s arguments creates prohibited new matter and is not supported by the specification or figures as originally filed.

Claim Objections

Claims 1 and 3 are objected to because of the following informalities:

With respect to claim 1, line 5, "selected from the a second" should be corrected to "selected from a second";

With respect to claim 3, lines 1-2, "the the additional" should be corrected to "the additional".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 8, 14, 21-22, 25, 27-29, 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Ocampo patent number 6,030,078.

Ocampo'078 reads on these claims by disclosing the limitations therein including the following: a contact lens (abstract) comprising at least one surface comprising a base layer having a clear central area that overlays a lens wearer's pupil and a translucent color zone that overlays the lens wearer's iris (claim 11, column 2, line 48, Figures 1 and 2 i.e. the "non-opaque" portion is translucent as disclosed as covering the iris while the pupil portion can be left clear). It is believed that the translucent iris coloring of Ocampo'078 will inherently cover the entirety of the iris, this being reasonably based upon Ocampo'078 disclosing the "opaque" portion as being

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intermittently applied and not showing the “non-opaque” translucent portion as being intermittently applied. Ocampo’078 further discloses an additional layer as an opaque layer having a clear central zone and a color zone (column 2, lines 7-44, Figures 1 and 2). Ocampo’078 further discloses the additional color layer covering greater than about 90% of the iris (Figure 2); covering about 40-70% of the iris (Figure 1). The translucent color zone and the additional color layer of Ocampo’078 would inherently each be of a uniform color, this being reasonably based upon Ocampo’078 not disclosing this translucent layer and opaque color layer each having multiple colors. Ocampo’078 further discloses the additional color layer having circular shapes (Figure 1, column 3, lines 25-37).

Claims 1-4, 8, 10, 14, 17-18, 21-22, 25, 27-29, 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Ocampo publication number 2003/0025873.

Ocampo’873 reads on these claims by disclosing the limitations therein including the following: a contact lens (abstract) comprising at least one surface comprising a base layer having a clear central area that overlays a lens wearer’s pupil and a translucent color zone that overlays the entirety of the lens wearer’s iris (paragraph 0060, lines 10-15 within). Ocampo’873 further discloses an additional layer as an opaque layer or a translucent layer having a clear central zone and a color zone (paragraph 0069). Ocampo’873 further discloses the additional color layer covering greater than about 90% of the iris (see Figures such as Figures 3, 5C, 9, 11-14); covering about 40-70% of the iris (see Figures such as Figures 4, 5A, 5B, 7-8); the translucent color zone and the additional color layer each of a uniform color (paragraphs

0060 and 0069); the additional color layer having circular shapes or striae (see Figures and paragraph 0013); and the lens comprising the base color layer and two opaque layers and the additional color comprising one or more second translucent color layers each having a uniform color (paragraph 0069).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ocampo'078 or Ocampo'873 in view of Claussen et al patent number 4,733,959.

Ocampo'078 and Ocampo'873 disclose as is set forth above but do not specifically disclose the lens further comprising a clear pre-polymer layer. Claussen teaches that a colored contact lens can further comprise a clear pre-polymer layer for the purpose of providing the means of tinting the lens (column 1, lines 33-46).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the colored contact lenses of either Ocampo'078 or Ocampo'873 as comprising a clear pre-polymer layer since Claussen teaches that a colored contact lens can further comprise a clear pre-polymer layer for the purpose of providing the means of tinting the lens.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ocampo'078 or Ocampo'873 in view of Hahne et al patent number 5,455,641.

Ocampo'078 and Ocampo'873 disclose as is set forth above and further disclose that the lenses can be formed of soft contact lens material (Ocampo'078, column 7, line 42 and Ocampo'873 paragraph 0062) but do not specifically disclose the lens further comprising aquafilcon, etafilcon, genfilcon, or lenefilcon. Hahne et al teaches that a contact lens comprising a soft contact lens material can further comprise etafilcon for the purpose of providing a soft contact lens of improved comfort (column 1, lines 11-15, column 3, lines 36-41). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the soft contact lenses of either Ocampo'078 or Ocampo'873 as comprising aquafilcon, etafilcon, genfilcon, or lenefilcon since Hahne et al teaches that a contact lens comprising a soft contact lens material can further comprise etafilcon for the purpose of providing a soft contact lens of improved comfort.

Response to Arguments

Applicant argues that Rawlings'121 and Knapp'188 show only intermittent color areas for the base layer. While the examiner agrees with this, applicant's specification and figures apparently only support intermittent colors for the base layer as well. As set forth in the new matter rejection above, there is nothing within applicant's specification or Figures to support anything other than intermittent color areas i.e. to support the claimed (and assumed), "a translucent color zone that overlays the entirety of the lens wearer's iris, the translucent color zone comprising color throughout the entirety of the translucent color zone".

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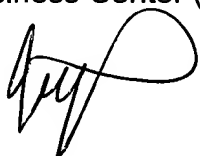
Furthermore, based upon the assumed meanings above, the rejections to Rawlings'121 and Knapp'188 have been withdrawn since both only disclose intermittent color. However, even with the assumed meaning, new art rejections are set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jordan M. Schwartz whose telephone number is (571) 272-2337. The examiner can normally be reached on Monday to Friday (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached at (571) 272-2328. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jordan M. Schwartz
Primary Examiner
Art Unit 2873
August 2, 2004